IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC, Plaintiffs, v. APOTEX INC. and APOTEX CORP., Defendants.	)	C.A. No. 07-792 (GMS)

PLAINTIFFS' ANSWERING BRIEF IN OPPOSITION TO DEFENDANTS' MOTION TO TRANSFER IN FAVOR OF PENDING FLORIDA JURISDICTION, OR IN THE ALTERNATIVE TO STAY THE DELAWARE ACTION

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Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") submit this brief in opposition to Defendants Apotex Corp. and Apotex Inc.'s (collectively "Apotex") motion to transfer this action to the Southern District of Florida, or in the alternative, to stay this case pending final resolution of that action. As Apotex has failed to show that balancing the *Jumara* factors favors transfer from Delaware—the first-filed forum and Plaintiff's forum of choice—to Florida, the Court should retain this action for coordinated proceedings with two related cases pending before the Court against 13 other defendants.

NATURE AND STAGE OF THE PROCEEDINGS

This is an action brought under the Hatch-Waxman Act for the infringement of a patent covering the drug Uroxatral® by the filing of an Abbreviated New Drug Application ("ANDA") seeking FDA approval of a generic version of that drug. The pleading stage of this action is complete and the parties await an order setting the initial case management conference from the Court.

SUMMARY OF THE ARGUMENT

Apotex has not met its burden of demonstrating that the balance of the interests of justice and the convenience of the parties and witnesses favors transfer to Florida. Delaware is Plaintiffs' forum of choice and the first-filed forum, not only for the suit against Apotex, but also for their claims against 13 other defendants. Plaintiffs would not have even filed the second action in Florida if Apotex had timely confirmed what it has now admitted in its pleadings — that it does not contest personal jurisdiction in Delaware and that venue is appropriate in this forum. Contrary to Apotex's assertion, plaintiffs' choice of forum and the first-filed rule apply even where the plaintiff filed both actions and courts have now widely recognized the necessity of filing so-called "protective suits" in ANDA cases in response to the ambiguities surrounding jurisdictional challenges under the Hatch-Waxman regime.

Rather than proceeding in Delaware where actions are currently pending against all accused infringers, Apotex seeks to game the system and engage in forum-shopping by arguing that the Southern District of Florida is more convenient and will adjudicate the parties' claims more quickly. There is scant support for either of these assertions. Apotex has failed to identify a single witness or document located in Florida. Instead, Apotex admits that it prepared and filed its ANDA from its offices in Canada. Moreover, the issues involved in this patent litigation are sufficiently complex, and potential discovery so far-reaching, that they will likely take a considerable time to adjudicate regardless of the forum in which they proceed.

If Apotex's attempt to make an end-run around sanofi-aventis's choice of forum is successful, the result will be contrary to the interests of justice, leading to a waste of judicial resources as well as the resources of the parties on duplicative discovery and other pretrial proceedings, potentially inconsistent rulings on issues that impact the certainty of patent rights, as well as great inconvenience to the parties and witnesses. Apotex's strategy would not only impact the parties in this case, but also the 13 additional defendants now before the Court where sanofi-aventis's other related patent infringement actions will proceed regardless of what happens with respect to sanofi-aventis's claims against Apotex. Consequently, the Court should follow the time-honored rule of allowing actions to proceed in the first-filed forum and retain this case so that all claims for patent infringement against all 15 defendants may proceed in the same court and before the same Judge and Magistrate Judge in a coordinated manner.

STATEMENT OF FACTS

I. The Parties

Plaintiff sanofi-aventis is one of the world's leading innovators in the research, development and marketing of drugs and vaccines. It is a French corporation with places of business throughout the world, including its principal place of business in Paris, France. *See* D.I.

1 ¶ 1. Plaintiff sanofi-aventis U.S. LLC is sanofi-aventis's United States affiliate. It is a Delaware Limited Liability Company with its North American headquarters in New Jersey. *See* D.I. 1 ¶ 2.

Defendant Apotex Inc. is a Canadian Company, with a place of business in Toronto, Ontario, Canada. *See* D.I. 7 ¶ 3. Defendant Apotex Corp. is a Delaware Corporation, and has places of business in a number of states, including Florida, New York and Indiana. *See* D.I. 7 ¶ 4. Apotex Inc. and Apotex Corp. sell generic drugs throughout the United States, including Delaware; according to Apotex Inc.'s website, "worldwide sales of the Apotex Group of companies exceed $1 billion (Canadian $) per year." Ex. A, The Apotex Group Corporate Info.[1]

II. Sanofi-aventis's Patents And Innovator Drug

Plaintiff sanofi-aventis is the current assignee of United States Patent No. 4,661,491 ("the '491 patent"), titled "Alfuzosine Compositions and Use." D.I. 1 ¶ 11. It is also a current assignee of United States Patent No. 6,149,940 (issued November 21, 2000), titled "Tablet with Controlled Release of Alfuzosine Chlorhydrate."[2] D.I. 8 ¶ 12. Both patents are listed in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral® brand alfuzosin hydrochloride 10 mg extended release tablets, the innovator drug for which Plaintiff sanofi-aventis U.S. LLC holds New Drug Application ("NDA") No. 21-287. D.I. 1 ¶ 11; D.I. 8 ¶ 13.

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1 True and accurate copies of the exhibits cited herein are attached to the accompanying Declaration of William T. Vuk in Support of Plaintiffs' Answering Brief In Opposition To Defendants' Motion To Transfer In Favor Of Pending Florida Jurisdiction, Or In The Alternative To Stay The Delaware Action.

2 Non-party Jagotec AG is also a current assignee of the '940 patent. Plaintiff sanofi-aventis has an exclusive license to Jagotec AG's interests in the '940 patent. D.I. 8 ¶ 12.

III. Infringement Of Sanofi-Aventis's Patents By The ANDA Filers

In the Summer of 2007, nine separate ANDAs for generic versions of Uroxatral® were submitted by, on behalf of, or with participation from 15 entities, to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), including ANDA 79-013 filed by Apotex Inc. with the participation and/or contribution of Apotex Corp. Each of these ANDAs seeks FDA approval for the commercial manufacture, use and sale of the ANDA filer's proposed generic product prior to the expiration of one or both of sanofi-aventis's patents. As part of each ANDA, the ANDA filers included "paragraph IV certifications," alleging that the claims of the '491 patent and/or the '940 patent are invalid and/or not infringed by the manufacture, use or sale of the proposed generic products. Sanofi-aventis received notification of the ANDAs and paragraph IV certifications in letters dated between August 14, 2007 and October 25, 2007, including notification of Apotex's ANDA and '940 patent paragraph IV certification by letter dated August 14, 2007 and notification that Apotex amended its ANDA to include a '491 patent paragraph IV certification by letter dated October 25, 2007. Ex. B, 08/14/07 B. Sherman ltr to Plaintiffs and Jagotec AG; Ex. C, 10/25/07 B. Sherman ltr to Plaintiffs and Jagotec AG.

The submission of these ANDAs and paragraph IV certifications permitted sanofi-aventis to sue for infringement of the '491 patent and/or the '940 patent. *See* 35 U.S.C. § 271(e)(2)(A). To litigate this infringement under the protections provided by the Hatch-Waxman Act, which affords a 30-month stay of generic approval while a patent litigation is pending, sanofi-aventis was required to file an action against each submitting party or parties within forty-five days of receiving notice of their respective paragraph IV certifications. 21 U.S.C. § 355(j)(5)(B)(iii).

IV. Commencement Of The First-Filed District Of Delaware Actions

A. Plaintiffs Initially Sued 13 Defendants For Infringement of the '491 and/or '940 Patents In This District

After receiving notice of the ANDAs and paragraph IV certifications, sanofi-aventis evaluated various personal jurisdiction issues and determined that the most logical venue for litigating its claims against all 15 potential defendants, including Apotex, was the District of Delaware. In light of this fact and the judicial economy and efficiency of having the same court try sanofi-aventis's claims against every defendant, sanofi-aventis commenced Civil Actions Nos. 07-572 (GMS) (MPT) and 07-574 (GMS) (MPT) on September 21, 2007 in this District against 13 defendants for infringement of the '491 and/or the '940 patent by the filing of their respective paragraph IV certifications.[3] *See* Ex. D, Delaware Complaint No. 07-572; Ex. E, Delaware Complaint No. 07-574.

B. Plaintiffs Sued Apotex For Infringement Of The '491 Patent In This District Shortly Thereafter

At the time of filing the first two Delaware complaints, Apotex's ANDA only included a paragraph IV certification against the '940 patent. *See* Ex. B. In reliance on Apotex's representations regarding its proposed generic product, sanofi-aventis informed Apotex that it would not file an action for infringement of the '940 patent unless Apotex's representations were incorrect or Apotex amended its ANDA to change the composition of its proposed generic product. Ex. F, 10/01/07 W. Vuk ltr to B. Tao. Sanofi-aventis then received a second paragraph IV certification from Apotex dated October 25, 2007, alleging that its proposed generic product did not infringe any valid claim of the '491 patent. Ex. C. In response, sanofi-aventis commenced Civil Action No. 07-792 (GMS) (MPT) against Apotex for infringement of the '491

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3 In these two actions, sanofi-aventis asserted both patents against nine defendants and the '940 patent alone against four additional defendants.

patent in this District on December 6, 2007. D.I. 1. That action was designated as related to the earlier-filed complaints and assigned to the same Judge and Magistrate Judge.

C. Apotex Agreed Not To Contest Jurisdiction In Delaware Only After The Expiration Of Plaintiffs' 45-Day Window To Bring Suit

Despite having previously admitted personal jurisdiction in several prior actions in this forum,[4] Apotex ignored sanofi-aventis's request to consent to jurisdiction prior to the expiration of the 45-day window to bring suit under the Hatch-Waxman Act. *See* Ex. H, 12/06/07 W. Vuk ltr to B. Sherman. It was only after the 45 days had run that Apotex stated that it would not contest jurisdiction in Delaware. Ex. I, 12/11/07 M. Noreika email to S. Rollo; Ex. J, 12/31/07 M. Noreika ltr to S. Rollo. On January 2, 2008, Apotex answered the Delaware complaint and conceded that jurisdiction and venue were proper in this forum:

- "Apotex Corp. admits that [the Delaware] Court has personal jurisdiction over it in this District for the purposes of this action." D.I. 7 ¶ 7;
- "For purposes of this action, Apotex Inc. does not contest the [Delaware] Court's jurisdiction over it . . . ." *Id.* ¶ 8;
- "Apotex Inc. and Apotex Corp. do not dispute this judicial district is a possible venue for this action . . . . " *Id.* ¶ 10.

Nevertheless, Apotex indicated that it would move to transfer the first-filed Delaware action to the Southern District of Florida because that is "a more convenient venue" and "will proceed more quickly to resolution." *See* D.I. 7 ¶ 10; Ex. K, 01/07/08 S. Feldman ltr to W. Vuk; Ex. L, 01/07/08 W. Vuk ltr to S. Feldman.

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4 On at least four separate occasions with respect to other ANDA litigations, Apotex has admitted that the District of Delaware has jurisdiction over it. Ex. G, Answer in *Allergan, Inc. v. Apotex Inc. et al*, Civ. No. 07-278-GMS at 2-3; Answer in *Medpointe Healthcare Inc. v. Apotex Inc.* et al. No. Civ. 07-204-SLR at 3**;** Answer in *Medpointe Healthcare Inc. v. Apotex Inc. et al.*, No. Civ. 06-164-SLR at 3-4; Answer in *Merck & Co., Inc. v. Apotex Inc.*, No. Civ. 06-230-GMS at 2. In fact, Apotex has also availed itself of the Delaware court as a plaintiff. Ex. G, Complaint in *Torpharm Inc. et al. v. Pfizer Inc. et al.*, No. Civ. 03-990-SLR at 4**.**

All three earlier-filed Delaware actions are designated as related cases and all are proceeding before Your Honor and Magistrate Judge Thynge. As of January 7, 2008, all 15 defendants, including Apotex, had filed their answers and counterclaims and sanofi-aventis had filed all of its replies.

V. Plaintiffs Brought The Second-Filed Florida Action To Protect Their Rights Under The Hatch-Waxman Regime In Response To Apotex's Failure To Confirm That It Would Not Contest Jurisdiction In Delaware

Apotex's refusal to consent to jurisdiction in this District within the 45-day window to bring suit placed sanofi-aventis in a significant dilemma. Under the Hatch-Waxman Act, a patentee has a "strict statutory 45-day window" in which to file an infringement action after receiving notice that an ANDA has been filed seeking approval to market a generic version of a patented drug product. *Abbott Labs. v. Mylan Pharm., Inc.*, No. 05 C 6561, 2006 WL 850916, at *8 (N.D. Ill. Mar. 28, 2006) (citing 21 U.S.C. § 355 (j)(5)(B)(iii)).[5] Sanofi-aventis met this deadline with respect to 13 defendants by its September 21, 2007 complaints in this Court and with respect to Apotex by its December 6, 2007 complaint in this Court. But it is unclear whether a patentee still enjoys the benefits of a suit under the Hatch-Waxman Act (as opposed to a suit for infringement generally under the patent laws) if its action, properly brought within the 45-day window, is dismissed for lack of personal jurisdiction after the 45-day period has expired. *See, e.g., PDL BioPharma, Inc. v. Sun Pharm. Indus., Ltd.*, No. 07-11709, 2007 WL 2261386, at *2 (E.D. Mich. Aug. 6, 2007); *Abbott*, 2006 WL 850916, at *8.

Although sanofi-aventis believed that this Court could properly exercise personal jurisdiction over Apotex, the Southern District of Florida was the only district in which sanofi-aventis knew Apotex would not contest personal jurisdiction based on prior litigation conduct

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5 Ex. T is a compendium of unreported cases cited herein.

and representations made in Apotex's certification letters. *See* Exs. B, C. Given the uncertain consequences surrounding the unlikely, but possible dismissal of the Delaware action, sanofi-aventis had no choice but to bring the second-filed Florida action within the 45-day window on December 10, 2007.[6] Ex. M, Florida Complaint. Plaintiffs made their intention in filing the second suit entirely clear in the complaint itself:

> Plaintiff's have sought to enjoin Defendant Apotex Inc.'s and Defendant Apotex Corp.'s infringing activities in an action filed by Plaintiffs in the District of Delaware on December 7, 2007, Civil Action No. 07-792 and will seek to have that action coordinated or consolidated with an action brought to enjoin acts of infringement of the '491 patent by numerous defendants filed by Plaintiffs in the District of Delaware on September 21, 2007, Civil Action No. 07-572 GMS (MPT). Defendant Apotex Inc. and Defendant Apotex Corp. are properly subject to personal jurisdiction in the District of Delaware and judicial economy would be promoted by all of Plaintiffs' claims for infringement of the '491 patent being addressed in the District of Delaware. ***Upon information and belief, Plaintiffs understand that Defendants may nevertheless contest jurisdiction in that venue. Given the possible consequences if Defendants succeeded with such unjustified action, Plaintiffs had no choice but to file this Complaint. In the event that Defendants are unsuccessful in any such challenge, Plaintiffs will dismiss this action.***

Ex. M ¶ 19 (emphasis added). Plaintiffs never served the Florida complaint on Apotex. As discussed above, Apotex subsequently agreed not to contest jurisdiction in Delaware, but would not confirm that agreement in writing before answering in Florida so that sanofi-aventis could voluntarily dismiss that complaint. Plaintiffs have since moved to transfer the Florida action to this District, or in the alternative, to stay the Florida action pending the resolution of the venue dispute by this Court. Ex. N, Plaintiff's Florida Motion To Transfer Or Stay.

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6 The consequences of losing the protections of the Hatch-Waxman Act are significant to the parties and the courts. Under the Act, approval of the proposed generic product is stayed by the FDA for 30 months and the action can be litigated in an orderly fashion without any damages issues or questions of emergency injunctions. 21 U.S.C. § 355(j)(5)(B)(iii); *Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 344 (D.N.J. 2003) ("The purpose of the 30-month stay is to allow time for patent infringement litigation."); *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 579 (D.N.J. 2001). Absent these protections, cases can devolve into free-for-alls with generic defendants seeking to launch "at-risk" and patentee plaintiffs seeking temporary restraining orders, preliminary injunctions and significant damages.

It is now clear that Apotex sought to make an end run around Plaintiffs' choice of this forum. Apotex filed its Answer and Counterclaims in the Florida action on December 28, 2007, one business day before answering the first-filed Delaware complaint.[7] *See* Ex. O, Florida Answer And Counterclaims; Ex. P, Florida Amended Answer And Counterclaims. It appears that Apotex's strategy was to ignore sanofi-aventis's inquiry as to whether it would contest jurisdiction in Delaware, in an effort to force sanofi-aventis to file a protective action in Apotex's forum of choice. Apotex now seeks to buttress its argument that Florida is "more convenient" with the "fact" that the Florida action has progressed farther than the Delaware actions, arguing that the Florida action is well underway even though the Florida court has not held its initial case management conference and the parties have only exchanged initial disclosures. Ex. Q, Defendants Apotex Inc.'s and Apotex Corp.'s Rule 26(a)(1) Initial Disclosures; Ex. R, 01/17/08 W. Vuk ltr to S. Feldman and S. Bronis; Ex. S, Plaintiffs' Initial Disclosures Pursuant to Rule 26(a)(1). Notably, Apotex has failed to identify a single witness or document located in the Southern District of Florida. Ex. Q. As discussed below, similar attempts by ANDA filers to game the system and to secure the forum of their choice at the expense of the plaintiff have been rejected.

ARGUMENT

I. All Relevant Factors Favor Proceeding In Delaware In Coordination With Related Claims Against 13 Other Defendants

Where venue is proper, a federal court, "[f]or the convenience of parties and witnesses, in the interest of justice, may transfer any civil action to any other district or division where it might

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7 In its Florida answer, Apotex "den[ies] that Apotex Inc. is subject to personal jurisdiction in the Delaware action . . . ." Ex. O ¶ 19. Apotex then contradicted that denial in its Delaware Answer, stating that it does not contest this Court's personal jurisdiction over Apotex Inc. D.I. 7 ¶ 8; *see also* Ex. I; Ex. J.

have been brought." 28 U.S.C. § 1404(a). Thus, the question of whether to transfer is a two-part inquiry. First, the transferee forum must be one in which the action could originally have been brought. Second, the Court must balance factors such as the plaintiff's choice of forum, the interests of justice, and the convenience of the parties and witnesses in deciding whether on the whole they favor transfer. *Jumara v. State Farm Ins. Co.*, 55 F. 3d 873, 879 (3d Cir. 1995). In the Third Circuit, courts consider both private and public interests in this balancing:

> The private interests have included: plaintiff's forum preference as manifested in the original choice, the defendant's preference, whether the claim arose elsewhere, the convenience of the parties as indicated by their relative physical and financial condition, the convenience of the witnesses-but only to the extent that the witnesses may actually be unavailable for trial in one of the fora; and the location of books and records (similarly limited to the extent that the files could not be produced in the alternative forum).
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> The public interests have included: the enforceability of judgment, practical considerations that could make the trial easy, expeditious, or inexpensive, the relative administrative difficulty in the two fora resulting from court congestion, the local interest in deciding local controversies at home, the public policies of the fora, and the familiarity of the trial judge with the applicable state law in diversity cases.

Id. at 879-80 (internal citations omitted). As the moving party, Apotex bears a heavy burden: unless the balance of these factors is in strong favor of transfer, a plaintiff's choice of forum should prevail. *See id.* at 879*; ZF Meritor LLC v. Eaton Corp.*, Civ. No. 06-623-SLR, slip op. at 2-3 (D. Del. June 13, 2007).

The parties do not dispute that this action could proceed either in this jurisdiction, where Apotex has agreed that it will not contest jurisdiction and that venue is appropriate, or in the Southern District of Florida. The only issue for the Court to decide is whether the balance of the *Jumara* factors heavily favors transfer to Florida. According to Apotex, transfer is warranted because (1) plaintiff's choice of forum and the first-filed rule do not apply when the plaintiff brought both actions against the same defendant; (2) transfer will "enforce the intent" of the Hatch-Waxman Act of getting inexpensive generic drugs into the hands of consumers as soon as

possible because the Florida action will be tried in October 2008; and (3) Florida is the more convenient forum and the locus of operative events. Apotex fails to meet its burden for each of these arguments under the relevant law and facts.

A. Both the Plaintiffs' Choice of Forum and the First-Filed Rule Favor Delaware

Plaintiff's choice of forum weighs against transfer and should not be disturbed if the relevant factors are evenly balanced or weigh only slightly in favor of the transfer. *Cont'l Cas. Co. v. Am. Home. Assurance Co.*, 61 F. Supp. 2d 128, 131 (D. Del. 1999). In fact, "plaintiff's choice of forum is of paramount consideration," even if that jurisdiction is not considered the party's "home turf." *Pernod Ricard USA, LLC v. Bacardi U.S.A., Inc.*, No. CIV 06-505-SLR, 2006 WL 3755452, at *2 (D. Del. Dec. 19, 2006). Retention of this case also comports with the Third Circuit's "first-filed" rule, which has been applied to "protective suits" brought under the Hatch-Waxman Act in this district. *Celgene Corp. v. Abrika Pharm., Inc.*, Civ. No. 06-741-SLR, slip op. at 1 (D. Del. Jul. 18, 2007). Under that standard, based on the principles of comity, if two actions involving the same parties and identical issues are pending in different districts, the first-filed action should typically be given priority and be allowed to proceed in favor of the later action. *EEOC v. University of Pennsylvania*, 850 F.2d 969, 971 (3d Cir. 1988).[8]

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8 The first-filed rule is measured by which action was filed first, not by when counterclaims are first-filed. Consequently, Delaware is the first-filed forum in this case, even though Apotex's counterclaims with respect to the '940 patent were filed in Florida one business day before filing them in this District. *See Kimberly-Clark Corp. v. McNeil-PPC, Inc.*, 260 F. Supp. 2d 738, 740-41 (E.D. Wis. 2003) (rejecting a similar argument concerning declaratory judgment counterclaims asserted in the second-filed action concerning patents not initially at issue in the first-filed action because "[t]he issue, however, is not which of the claims was filed first, but rather which action was filed first."); *Versus Tech., Inc. v. Hillenbrand Indus., Inc.*, No. 1:04-CV-168, 2004 WL 3457629, at *6-7 (W.D. Mich. Nov. 23, 2004); *cf. Holmes Group, Inc. v. Vornado Air Circulation Sys. Inc.*, 535 U.S. 826, 831-32 (2002) (holding that counterclaims cannot serve as the basis for "arising under" jurisdiction under the well-pleaded complaint rule).

Sanofi-aventis filed the Delaware action against Apotex on December 6, 2007. The Florida action was filed on December 10, 2007, but never served. Both the Delaware and the Florida actions raise the same issues—namely, whether Apotex's proposed generic version of Uroxatral® infringes any valid and enforceable claim of the '491 patent, and to the extent Apotex's counterclaims are not dismissed, whether that product infringes any valid and enforceable claim of the '940 patent. Sanofi-aventis had a rational and legitimate reason to choose the District of Delaware because it was the district where Plaintiffs could bring each of the 15 ANDA filers and related defendants under the jurisdiction of the court so that all claims and counterclaims concerning Uroxatral® and the listed patents could be adjudicated in a single forum. *Auto. Techs. Int'l, Inc. v. Amer. Honda Motor Co., Inc.*, No. 06-187 GMS, 2006 WL 3783477, at *2-3 (D. Del. Dec. 21, 2006) (denying motion to transfer where plaintiff had a rational and legitimate reason to sue defendants in the forum because, *inter alia*, all parties were subject to personal jurisdiction in that forum); *see also Joint Stock Soc'y v. Heublein, Inc.*, 936 F. Supp. 177, 187 (D. Del. 1996). This District is also where two of the parties, Apotex Corp. and sanofi-aventis U.S. LLC, are incorporated. *See Auto. Techs.*, 2006 WL 3783477 at *2.

Apotex argues that these time-honored rules should be ignored where the "plaintiff chooses to file two identical lawsuits against the same party in two different venues" to support its spurious allegation that Plaintiffs cannot claim hardship because they chose to file a second action in Florida. *See* D.I. 11 at 11, 13. Apotex has not cited any authority that would support the application of such a mechanical limitation on the first-filed rule in this jurisdiction; in fact it would be contrary to the efficient administration of justice through the principles of comity which form the basis of the rule. Moreover, Apotex's proposed carve-out completely ignores the specific jurisdictional issues inherent to ANDA litigations that various district courts have

recognized force patentees to file protective suits to ensure that they will be entitled to the benefit of a 30-month stay under the Hatch-Waxman Act.

For example, the court in *PDL Biopharma, Inc. v. Sun Pharmaceutical Ind., Ltd.* was faced with a similar situation in which the patentee and NDA holder PDL moved to stay its second-filed "protective action" based on the "first-filed" rule. No. 07-11709, 2007 WL 2261386, at *2 (E.D. Mich. Aug. 6, 2007). ANDA filer Sun opposed the motion arguing that the "first-filed" rule should not apply because PDL was allegedly motivated by bad faith or forum shopping. Concerned that going forward with two identical actions simultaneously would waste scarce judicial resources and present the distinct possibility of conflicting rulings or judgments, the court overseeing the second-filed action held that application of the first-filed rule was appropriate and granted the stay. *Id.* at *2. The court rejected Sun's complaints of bad faith and forum shopping stating that:

> Plaintiff filed the duplicative actions only because of the extraordinary time limit placed on the filing of suits under the Hatch-Waxman Act. Plaintiff correctly believed that Defendant would challenge personal jurisdiction in Plaintiff's preferred forum and concluded that, should a court in Plaintiff's preferred forum of the District of New Jersey find that jurisdiction was not appropriate there, the timing of the ruling could preclude Plaintiff from filing *any* action under the Act. ***These circumstances do not demonstrate bad faith or forum shopping on the part of Plaintiff. Furthermore, given the strict deadline and the potentially harsh outcome should Plaintiff's preferred forum dismiss the cause of action after the deadline, a consideration of the 'extraordinary circumstances' of the case weighs in favor of the stay.***

Id. (emphasis added). "[G]iven the unusual nature of ANDA claims and absent any guidance," the court found that plaintiff had satisfied its burden for a stay. *Id.*; *Abbott*, 2006 WL 850916 at *8 ("The [Hatch-Waxman Act] is silent, and the courts have not clarified, whether the patent holder loses its right to sue for patent infringement in the event its suit is dismissed for lack of personal jurisdiction after the 45-day period has expired.").

Courts in the Third Circuit have made similar findings. For example, in *Celgene Corp. v. Abrika Pharm., Inc.,* plaintiffs brought suit for patent infringement under the Hatch-Waxman Act against defendants in the District of New Jersey. No. 06-5818, 2007 WL 1456156, at *1 (D.N.J. May 17, 2007). Plaintiffs filed a nearly identical action two days later in the District of Delaware. *Id.* Recognizing plaintiffs' choice of forum and the first-filed rule, the court declined to transfer the first-filed New Jersey action to Delaware where "Plaintiffs had a legitimate reason to file a similar, even identical action in Delaware, in order to ensure that they would not be time-barred from bringing the action at all should this Court find that it did not have personal jurisdiction over Defendants." *Id* at *4*; see also Aventis Pharma S.A. v. Sandoz Inc.*, No. 06-3671 (MLC), 2007 WL 1101228, at *3 (D.N.J. Apr. 10, 2007) ("Aventis's explanation that it filed a virtually identical complaint in New Jersey after filing in California in case Sandoz contested in personam jurisdiction in California and to preserve its rights to a 30-month stay of FDA approval of Sandoz's application sufficiently refutes any allegation of judge or forum shopping by Sandoz."); *cf. Medpointe Healthcare Inc. v. Cobalt Pharm. Inc.*, No. 07-4017 (JAP), slip op. at 3 (D.N.J. Jan. 28, 2008) (denying transfer from the first-filed forum even though plaintiff had filed both the initial ANDA patent infringement action and the second "protective" suit against the same defendant). The court went on to note that plaintiffs had filed the New Jersey action first, and as here, had not served the complaint in the second-filed Delaware action, "indicating a clear preference that the case move forward in New Jersey." *Id.* Judge Robinson agreed and dismissed the second-filed action as she was "not persuaded that the facts of this case warrant an exception to the 'first filed rule.'" *Celgene Corp. v. Abrika Pharm., Inc.,* Civ. No. 06-741-SLR, slip op. at 1 (D. Del. Jul. 18, 2007).

The facts here are identical in all relevant respects to those in *PDL* and *Celgene*. Sanofi-aventis was forced by Apotex's refusal to consent to jurisdiction in Delaware until after the 45-day period for bringing suit—and the lack of guidance in the statute and case law regarding the effect of the possible dismissal of a suit for lack of personal jurisdiction on a patentee's Hatch-Waxman rights—to file a "protective action" in Florida. *See, e.g.*, Ex. H; Ex. M ¶ 19. Sanofi-aventis had a reasonable basis for concluding that Apotex is subject to jurisdiction in the District of Delaware, including Apotex Corp.'s incorporation here and Apotex's prior admissions in other ANDA litigations, which has been confirmed by Apotex's subsequent representations to the Delaware court that it will not challenge jurisdiction. *See* Ex. G; D.I. 7. Apotex can hardly argue that sanofi-aventis's filing of parallel actions are motivated by bad faith or forum shopping. Now that Apotex has acknowledged that it does not contest personal jurisdiction in Delaware, the Court should move forward with this action in Plaintiffs' forum of choice and not allow Apotex's gamesmanship to dictate where Plaintiffs' claims will proceed.

None of the cases cited by Apotex to support its argument are binding or even persuasive authority. In *Aventis Pharma Deutschland GMBH v. Lupin Ltd*., the Virginia court based its ruling on the erroneous holding that the first-filed rule was limited to the race-to-the-courthouse situation, and did not apply to two suits filed by the same plaintiff. 403 F. Supp. 2d 484, 489-90 (E.D. Va. 2005). Moreover, it stated that plaintiffs in that case did "not explain why or if the [Hatch-Waxman Act] requires such a 'protective measure.'" *Id*. at 490.

This case is readily distinguishable from *Lupin.* As an initial matter, precedent from this District clearly shows that the first-filed rule is certainly not subject to the mechanical limitation imposed by the *Lupin* court. *See, e.g., Celgene Corp. v. Abrika Pharm., Inc.*, Civ. No. 06-741-SLR, slip op. at 1 (D. Del. Jul. 18, 2007); *see also Airport Investors Ltd. P'ship, Inc. v. Neatrour*,

No. 03-831 GMS, 2004 WL 225060, at *2 (D. Del. Feb. 3, 2004) (recognizing that, although not addressed by the parties, "the 'first-filed' rule of this Circuit likely dictates" transfer of the second-filed Delaware action to the first-filed forum even though plaintiffs brought both actions against defendants). Moreover, defendants in *Lupin* contested jurisdiction in the first-filed forum; here, Apotex has stated that it will not contest jurisdiction in Delaware. *Aventis*, 403 F. Supp. 2d at 490; D.I. 7 ¶¶ 7-8, 10. And here, there are related actions pending in this first-filed forum that will proceed regardless of where the Apotex case is tried—a key fact not at issue in *Lupin.* Finally, Plaintiffs have made clear that their sole reason for filing in Florida was to protect their rights due to the ambiguities concerning personal jurisdiction challenges in ANDA cases. Ex. M ¶ 19. District courts post-*Lupin*, such the *PDL*, *Celgene*, and *Abbott* courts discussed above, have clearly recognized the need for filing protective suits under the Hath-Waxman Act and have expressly rejected the Virginia court's limitation on the first-filed rule. *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, No. 1:07-cv-993, 2007 WL 4284877, at *2 (W.D. Mich. Dec. 3, 2007) (refusing to apply the *Aventis* court's "mechanical limitation" and noting "the harsh outcome should [the first-filed forum] dismiss the cause of action after the 45 day filing period, the extraordinary circumstances of the case weigh in favor of granting the stay" of the second-filed action).

Apotex also relies on a letter opinion from *Adams Respiratory Therapy v. Mutual Pharmaceutical Holdings*, Civil Action No. 06-4418 HAA, slip op. (D.N.J. Nov. 16, 2006), to support its position. D.I. 11 at 12-13. The primary concern of the *Adams* court, however, was judge shopping. D.I. 11-2 at Ex. D at 2. Here, Plaintiffs were not judge shopping, but were merely trying to ensure that their claims would go forward if Apotex successfully challenged personal jurisdiction in Delaware. Plaintiff's intention was clear—they sought Apotex's consent

to jurisdiction in Delaware prior to filing the Florida action and never served the Florida complaint on Apotex. Exs. H, M ¶ 19. And as in *Lupin*, the judge in *Adams* did not appreciate the specific jurisdictional issues relevant to ANDA actions and the serious consequences patentees face due to the ambiguities in the statute and case law concerning those issues if they do not file second, "protective" suits in certain circumstances. Moreover, the *Adams* opinion has not been followed in the issuing forum as the *Celgene* decision discussed above shows. [9]

B. The Interests of Justice Can Only Be Served By Litigating In Delaware Where All Others Claims Concerning The Patents Are Pending

Alternatively, Apotex argues that the Court should transfer under an exception to the first-filed rule to expedite the resolution of the parties' claims and to the serve the convenience of its witnesses. D.I. 11 at 12. As discussed below, there is little support for either of these arguments and they are greatly outweighed by the interests of justice in litigating the patent claims against all 15 defendants in the same forum.

As the Federal Circuit has held, "consideration of the interest of justice, 'may be determinative to a particular transfer motion, even if the convenience of the parties and witnesses might call for a different result.'" *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1565 (Fed. Cir. 1997). Courts have found that the interests of justice are best served when all of a patentees' claims for infringement proceed in the same forum to avoid a waste of judicial resources and prevent inconsistent rulings. Apotex brushes aside these significant considerations with general claims that the generic products and defenses in the related Delaware actions may

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9 The other cases cited by Apotex are no more persuasive. *See* D.I. 11 at 12. They do not address ANDA patent litigations or protective suits, but instead addressed issues concerning anticipatory declaratory judgment actions—a well-known exception to the first-filed rule. *See Employers Reinsurance Corp. v. MSK Ins., Ltd.*, No. Civ.A.01-2608-CM, 2003 WL 21143105, at *6-7 (D. Kan. Mar. 31, 2003); *Serco Services Co., L.P. v. Kelley Co., Inc.*, 51 F. 3d 1037, 1039 (Fed. Cir. 1995).

be different. Such unsupported hand waving does not obscure the fact that if the Apotex case proceeds in Florida, both this Court and the Florida court will have to manage discovery, pretrial proceedings such as claim construction, and eventually trial based on allegations of infringement and validity of the same patents for proposed generic products all referencing the same innovator product and its approved indication. The case law, and logic, demonstrate that the benefit of avoiding such duplication is hardly "illusory" as Apotex claims. *See* D.I. 11 at 9.

For example, in *Alere Medical, Inc. v. Health Hero Network, Inc.*, a first-filed action was brought in Illinois for infringement of plaintiff's patent. No. C- 07-05054 CRB, 2007 WL 4351019, at *1 (N.D. Cal. Dec. 12, 2007). The accused infringer subsequently filed a declaratory judgment action in California concerning seven other patents owned by the patentee, but not at issue in the first-filed action. The second-filed court granted the accused infringer's motion to transfer its declaratory judgment action to the first-filed forum because, *inter alia*, the related actions "share[] common technology and products, common parties, and overlapping issues of infringement and validity. Having all the patents before a single judge will obviate the need for duplicative tutorials and evidence, and will facilitate a global settlement." *Id.* Rejecting the patentee's argument that transfer would be inconvenient in light of the location of relevant witnesses, parties, and documents, the court stated that "the pertinent question is not simply whether *this* action would be more conveniently litigated in Illinois than California, but whether it would be more convenient to litigate the California and Illinois actions separately or in a coordinated fashion." *Id.* at *2; *Cordis Corp. v. Siemens-Pacesetter, Inc.*, 682 F. Supp. 1200, 1202 (S.D. Fla. 1987).

Likewise, in *Tingley Systems, Inc. v. Bay State HMO Management, Inc.*, the second-filed court granted defendant's motion to transfer to the first-filed forum even though defendant had

not proven that its witnesses would be more inconvenienced than plaintiff's witnesses without a transfer. 833 F. Supp. 882, 886 (M.D. Fla. 1993). What defendant had established, however, was that "all parties and witnesses would be greatly burdened if all were required to travel between two forums because the two related cases in which they were all involved were being tried in different states." *Id.* By transferring the second-filed action in the interest of justice, the court held that all the parties would benefit because:

> The two actions should be consolidated before one judge thereby promoting judicial efficiency, pretrial discovery could be conducted in a more orderly manner, witnesses could be saved the time and expense of appearing at trial in more than one court, duplicative litigation involving the filing of records in both courts could be avoided eliminating unnecessary expense and the possibility of inconsistent results could be avoided."

Id. at 888 (internal quotations omitted).

The facts that support proceeding in this Court are even more compelling here where sanofi-aventis has multiple suits pending in Delaware that share the same claims and counterclaims concerning the '491 and '940 patents. In addition to this action against Apotex, there are two other related cases concerning infringement of the same patents by eight additional ANDAs referencing Uroxatral®, which will proceed regardless of where the Apotex claims are tried. Each of these actions is pending before the same Judge and Magistrate Judge. All answers and replies have been filed and the parties now await an initial scheduling order and coordinated pretrial activities in all three pending cases to avoid duplicative discovery efforts and serve judicial efficiency.

By retaining this action for coordination with the other Delaware cases, the Court will avoid duplicating pretrial activities, thus preserving judicial resources and reducing costs for the parties. Apotex's attempt to argue that these efficiencies have no bearing on this case because there may be differences between its products and the other generics as well as the invalidity

arguments advanced by each defendant are unpersuasive. *See* D.I. 11 at 7-8. Based on the invalidity arguments presented by defendants in their paragraph IV certification letters, it appears that all are relying on the same or similar prior art references to argue that the claims of the patents-in-suit are invalid. Likewise, each of the proposed generic products is a purported once-a-day formulation referencing Plaintiffs' Uroxatral® product, including its proposed indication. As the issues with respect to Plaintiffs' activities concerning the reference product Uroxatral® and the patents-in-suit are identical, transfer would lead to multiple depositions of witnesses concerning the development of Uroxatral® and prosecution of the patents-in-suit, as well as all regulatory and marketing issues on which the defendants may seek discovery. Additionally, transfer would likely lead to duplicative discovery disputes concerning these issues being adjudicated by separate courts. Moreover, transfer to Florida would force two courts to learn the technology associated with the patents-in-suit, the alleged prior art, and the proposed generic products. *See Schering Corp. v. Caraco Pharm. Labs., Ltd.,* No. 06-14386, 2007 WL 1648908, at *3 (E.D. Mich. June 6, 2007) (staying second-filed action pending resolution of jurisdictional issues in first-filed court, *inter alia*, to avoid "the probable inefficiency and the potential for the misuse of the limited resources of the judiciary" where claims against 19 other ANDA defendants were pending in the first-filed forum).

Finally, retaining this case will prevent potentially inconsistent rulings on critical issues such as claim construction, the validity of the asserted claims, and, to the extent the ANDA filers allege similar defenses, whether the proposed generic products infringe those claims. This factor is especially important with respect to claim construction, where inconsistent rulings could result in the same claim terms having different meaning for different defendants. *See Cordis*, 682 F. Supp. at 1202; *cf. MLR, LLC v. U.S. Robotics Corp.,* No. 02 C 2898, 2003 WL 685504, at *1-2

(N.D. Ill. Feb. 26, 2003) (denying motion to stay under an exception to the first-filed rule in favor of the second action where patentee's claims for infringement were pending before all accused infringers and would proceed regardless of whether the stay was granted); *Eason v. Linden Avionics, Inc.*, 706 F. Supp. 311, 330 (D.N.J. 1989) ("[L]itigation of related claims in the same tribunal is strongly favored because 'it facilitates efficient, economical and expeditious pretrial proceedings and discovery and avoids [duplicative] litigation and inconsistent results.'").

C. Apotex's Unsupported Congestion Arguments Are Substantially Outweighed By The Other Relevant Factors

Apotex's only public interest counterargument is that under the Hatch-Waxman regime a "generic is entitled to expeditious judicial resolution of this matter to get its less expensive generic equivalents to market" and that Florida will reach resolution fastest. D.I. 11 at 5. As an initial matter, Apotex's evidence that the Florida action will reach resolution faster than this case is minimal at best. Although the Florida court has issued a scheduling order setting the trial date for October 2008, the parties have not had their initial case management conference with the judge and Plaintiffs will ask the Florida court to set a 2009 trial in the parties' joint status report filed in anticipation of that conference. Sanofi-aventis expects that the dates for discovery and trial will have to be pushed back to ensure that the parties' claims and defenses are fully-developed in a fair and efficacious manner. Moreover, no meaningful discovery has taken place in Florida. The parties have merely exchanged their initial disclosures and Apotex has served a set of document requests. *See* Exs. Q-S.

This is a complex litigation that will require the resolution of a variety of patent-specific issues, such as claim construction, infringement, and validity that will take a significant amount of time to adjudicate. Plaintiffs expect that Apotex will seek discovery on a wide-range of issues concerning the development of sanofi-aventis's inventions, patent prosecution, alleged prior art,

and various marketing and regulatory activities. Many of the hundreds of thousands of potentially relevant documents are decades old and are located overseas where they must be reviewed in compliance with the European Union and member-state privacy directives prior to transport to the United States. Considering the number of inventors and other potentially relevant witnesses, including third parties, Plaintiffs expect the parties to conduct a large number of depositions, some of which may require Apotex to seek relief under the Hague Convention. Consequently, this case will take a significant amount of time to resolve regardless of where it proceeds. Any additional time spent litigating does not necessitate transfer from Plaintiffs' choice of forum in light of the juridical economy and witnesses convenience benefits to retaining the case in this District for coordination with the other two related cases.

Moreover, getting low-cost drugs to market is not the only goal of the Hatch-Waxman Act. Rather, "Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F. 3d 1324, 1327 (Fed. Cir. 2005). The Act recognized the importance of patentees' rights by making the filing of an ANDA and paragraph IV certification an act of infringement and by providing for a 30-month stay of FDA approval so that the infringement actions could be litigated in an orderly fashion without any damages issues or questions of emergency injunctions. 21 U.S.C. § 355(j)(5)(B)(iii); *Dr. Reddy's Labs.*, 302 F. Supp. 2d at 343; *Ben Venue Labs.*, 146 F. Supp. 2d at 579. Requiring innovators such as sanofi-aventis to conduct duplicative litigation in multiple forums, as Apotex seeks to do, would result in increased costs to innovators, reducing their incentives to bring new drugs to market. This result would run counter to the intent of Congress and frustrate a key purpose of the Hatch-Waxman Act.

In any event, Apotex's conduct in the litigation to date demonstrates that the availability of low-cost drugs is not its concern. Apotex's gambit of aggressively pressing the Florida action while seeking to delay this case is motivated by the potential for significant financial gain to Apotex if it is able to enter the market with a generic copy of sanofi-aventis' Uroxatral® without competition from the other defendants.[10] Under these circumstances, allowing duplicative actions to proceed in parallel would provide Apotex with a powerful incentive to continue to delay resolution of the Delaware action, thereby in fact reducing the potential for the generic competition that Apotex purposes to espouse. Indeed, the resolution of Plaintiffs' claims will best be expedited under the Hatch-Waxman Act through cooperation between Plaintiffs and all 15 defendants to conduct discovery and other pretrial proceedings in an efficient and coordinated manner.

D. Apotex's Unsupported Convenience Arguments Do Not Favor Transfer Under *Jumara*

Finally, Apotex argues that it would be more convenient for the witnesses and the parties to proceed in the Southern District of Florida, because Apotex Corp. is based in that district. D.I. 11 at 2, 10; D.I. 7 ¶ 10; Ex. P ¶ 19. As the moving party, Apotex bears the burden of demonstrating that this factor, in the balance of the *Jumara* standard, so strongly favors transfer that Plaintiffs' choice of forum should be disturbed. Apotex doesn't even come close.

Apotex states that Apotex Corp., located in Florida, "will market and sell the allegedly infringing product" citing the declaration of Apotex Corp.'s president, Tammy McIntire, in

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[10] Apotex's delay is even evidenced by the timing of its present motion. Apotex first alerted the Court that it preferred the Southern District of Florida in its Answer and Counterclaims on January 2, 2008. D.I. 7 ¶ 10. Apotex then confirmed during a meet and confer with Plaintiffs on January 7 that it would move to transfer the present action to Florida. Ex. L. But Apotex waited another three weeks before filing this motion to transfer, after the parties exchanged their local rule disclosures in Florida and after Apotex was entitled to serve document requests in that action.

support. D.I. 11 at 2. Nothing in Ms. McIntire's barely 2-page declaration, however, supports this allegation. D.I. 13. In fact, the declaration does not identify a single event, witness, or document with any connection to Florida that is relevant to this case. Instead, Ms. McIntire merely says that :

> To the extent any Apotex Corp. employees are knowledge about ANDA NO. 79-013 they are employed at the Florida location.
>
> To the extent Apotex Corp. has any documents relevant to ANDA No. 79-013 they are located at Apotex Corp.'s Florida location.

Id. ¶¶ 5, 6. The declaration submitted by Apotex Inc.'s director of regulatory affairs, Bernice Tao, does not say much more. D.I. 12. The sole link to Florida provided by Ms. Tao is that Apotex listed Ms. McIntire in Weston, Florida as the agent for service in Apotex Inc.'s paragraph IV certification letters. *Id.* ¶ 9.

None of these facts weigh in favor of transfer under the *Jumara* convenience factors. Although Apotex has failed to name any witnesses or identify their locations in Florida, it is reasonable to assume that any such witnesses are likely employees of Apotex and could be made available for trial in either Florida or Delaware. *See Jumara*, 55 F. 3d at 879 (stating that the convenience of witnesses is only considered "to the extent that the witnesses may actually be unavailable for trial in one of the fora."); *Pernod*, 2006 WL 3755452 at *3; *Auto. Techs.*, 2006 WL 3783477, at *2 ("Further, as this court has previously held, a flight to Delaware is not an onerous task warranting transfer."); *see also Abbott*, 2006 WL 850916, at *7 ("In a case where all of the witnesses of the [generic] defendant will be its employees, however, the location is not as important a factor as it would be if the witnesses were not under the control of the defendant."). To the extent Apotex contends there are third parties with relevant knowledge in Florida, it has made no showing of who those witnesses are or that they would be unwilling or unable to travel to Delaware for trial; obviously, the parties can work together on a discovery schedule that

minimizes the travel burdens placed on third parties to the extent they must be deposed prior to trial. Likewise, the location of any documents in Florida does not favor transfer as Apotex has made now showing as to why those documents could not be produced in Delaware. *Jumara*, 55 F. 3d at 879*; Auto. Techs.*, 2006 WL 3783477, at *2 ("Here, the Defendants do not suggest that their documents could not be produced in Delaware, especially in this day and age where large-scale 'document' products are reduced to digitized records that parties transfer via electronic media. Accordingly, this factor does not weigh in favor of granting transfer.").

Moreover, these unsupported facts cited by Apotex to not establish that Florida was the situs of operative events that lead to the litigation. D.I. 11 at 10-11. Apotex admits that the Canadian company, Apotex Inc., prepared and filed the ANDA from its offices in Canada. D.I. 12 ¶ 5. Apotex does not allege that any of the research and development, patent prosecution, or marketing activities with respect to the reference drug Uroxatral took place in Florida. *Compare Alcon Mfg., Ltd. v. Apotex Inc.*, No. 1:06-cv-1642-RLY-TAB, 2007 WL 854026, at *2-3 (S.D. Ind. Mar. 14, 2007) (finding that operative events took places where Apotex prepared its ANDA and where plaintiffs conducted research and development) *to Bristol-Myers Squibb Co. v. Andrx Pharms., LLC,* No. 03 Civ. 2503 (SHS), 2003 WL 22888804, at *5 (S.D.N.Y. Dec. 5, 2003) (noting that the design and development of the allegedly infringing product occurred in the second-filed forum). To the extent that any of Apotex Corp.'s acts to induce or contribute to Apotex Inc.'s infringement occurred in Florida, this factor may marginally support transfer, but is vastly outweighed by Plaintiffs' choice of forum, the first filed-rule, the interests of judicial economy, and the convenience of the parties and witnesses.

Apotex is part of a multinational, billion dollar group of companies and has proceeded in Delaware in several other ANDA litigations, including at least one as a plaintiff, without moving

to transfer. *See, e.g., ZF Meritor LLC v. Eaton Corp.*, Civ. No. 06-623-SLR, slip op. at 3, (D. Del. June 13, 2007) (refusing to transfer where "[d]efendant is a billion-dollar company with nationwide operations that has litigated in Delaware on multiple occasions."); *Inpro II Licensing, S.A.R.L. v. T-Mobile USA, Inc.*, Civil Action No. 03-1047 GMS, slip op. at 4 (D. Del. Mar. 5, 2004) ("Moreover, short of invoking judicial estoppel, the court finds many of the Defendants' arguments in favor of these factors to be disingenuous considering that [one of Defendants] have brought infringement actions in the District of Delaware on five previous occasions in the last three years."); *see also Abbott*, 2006 WL 850916, at *8 (finding an ANDA filer's convenience argument less persuasive when it had litigated multiple ANDA cases in the forum without complaint). In addition, Apotex Corp. is a Delaware corporation. Having enjoyed the benefits of doing business under Delaware law, it cannot complain about proceeding in this judicial forum. Based on these facts, Apotex can surely be expected to bear any minimal, unsupported inconvenience of proceeding in Delaware as it would be greatly outweighed by the burden on sanofi-aventis of proceeding in two separate fora for discovery and other pretrial proceedings, as well as the burden on sanfoi-aventis's and third party witnesses who will likely be called for deposition by Apotex in Florida and by the other 13 defendants in Delaware.

Apotex recently tried unsuccessfully to transfer an ANDA infringement action from the Southern District of Indiana to the Southern District of Florida. *See Alcon*, 2007 WL 854026 at *2-3. The *Alcon* court rejected Apotex's arguments, including its convenience claims. First, the court found that Florida was not a more convenient forum because the parties were spread throughout the United States and internationally. Thus, any financial burden of proceeding in the first-filed forum was insufficient to overcome the deference in plaintiff's choice of forum, even though it was not the plaintiff's home district. *Alcon*, 2007 WL 854026, at *2-3. Second,

Apotex failed to show that transfer to Florida would be more convenient to the witnesses, as Apotex's development of its proposed generic product and preparation of the ANDA took place in Canada and plaintiffs' research and development of the patented product took place in Texas and Japan; thus, both parties' witnesses would have to travel to either the first- or second-filed forum, with the only apparent exception being the president of Apotex USA. *Id.*

The facts here are analogous to those in *Alcon* with a significant addition—there are related actions pending in this District that will proceed regardless of where Plaintiffs' claims against Apotex are litigated. If this case is transferred to Florida, both this Court and the Florida court will have to become experts in the technology-in-suit, construe the claims of the patents-in-suit, rule on summary judgment and generally manage discovery on identical issues. Additionally, sanofi-aventis will be forced to conduct the same pretrial activities in each forum while its witnesses and those of third parties are needlessly forced to appear for deposition in multiple actions. These public and private burdens substantially outweigh any claimed inconvenience to Apotex.[11]

II. As the First-Filed Forum, This Court Should Decide The Issue Of Venue And Not Stay This Case Pending Final Resolution Of The Florida Action

Apotex provides absolutely no argument or authority in support of its request that the Court stay this action—while the two related cases in this forum proceed—pending final resolution of the Florida action. D.I. 11 at 3, 14. Plaintiffs respectfully request that the Court

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[11] Balancing the remaining *Jumara* factors does not favor transfer as Apotex has made no showing that (1) either Florida or Delaware would not be able to enforce a judgment against any of the parties; (2) Florida has any specialized interest in resolving a federal patent dispute concerning drugs that are or would be sold throughout the country; (3) the public policies of Florida and Delaware differ with respect to the enforcement of patent rights or in balancing the competing interests of the Hatch-Waxman Act; or (4) that there are any state law issues that either the Florida or Delaware courts have more familiarity with.

retain this action for coordinated proceedings with the two related cases pending before it. Staying this action pending final resolution of the Florida case would mean that two courts will have to deal with the same issues if Plaintiffs must proceed in two fora at the same time. Plaintiffs have moved the Florida court to transfer the action before it to this District, or in the alternative, to stay that action pending this Court's resolution of the parties' venue disputes. Plaintiffs expect that the Florida court will transfer the case before it to this District or defer to this Court under the first-filed rule on deciding where this case should proceed.

CONCLUSION

For all the foregoing reasons, sanofi-aventis requests that the Court deny Defendants' motion to transfer this action to the Southern District of Florida or to stay this case pending final resolution of that second-filed case.

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January 31, 2008

CERTIFICATE OF SERVICE

I hereby certify that on January 31, 2008 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to:.

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I further certify that I caused to be served copies of the foregoing document on January 31, 2008 upon the following in the manner indicated:

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